DETAILED ACTION

Specification

1. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The specification fails to disclose beveling the guide tube proximal end at an angle formed by following a straight line from the union of the guide tube and the flared proximal end of the distal tube to the union of the guide tube and the deflected and inclined portion of the main tube.

Claim Objections

2. Claims 23-25 and 27 are objected to because of the following informalities: Claim 23 recites the limitations "the union of the guide tube and the flared proximal end of the distal tube" in lines 19-20 and "the union of the guide tube and the deflected and inclined portion of the main tube in lines 20-21. There is insufficient antecedent basis for these limitations in the claim. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 23, 24, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al (U.S. Patent No. 6,036,670) in view of Miraki (U.S. Patent 5,389,087) and in view of Dirks et al.

In Figure 2, Wijeratne et al show or provide a distal tube (22) with a flared proximal end (at 38), a guide tube (23) with a proximal end (26), and a main tube (32) with a distal end (37). As seen in Figure 2, a portion of the main tube near the distal end (37) of the main tube is deflected and inclined towards the axis of the main tube. The deflected and inclined portion (or at least part of the deflected and inclined portion) of the main tube (32) is inserted into the distal tube flared proximal end (100) so that a portion (at 26) of the guide tube (23) near the proximal end of the guide tube rests on a section of the outside of the deflected and inclined portion. Wijeratne et al teach joining or fixing the distal end (37) of the main tube, the proximal end (26) of the guide tube, and the flared proximal end (at 38) of the distal tube to one another by means of a heat-sealing operation (line 42 of column 5 to line 14 of column 6). As seen in Figure 2, the guide tube (23) is inserted into the distal tube (22) such that the guide tube proximal end (26) exits and extends from the distal tube flared proximal end (at 38). Wijeratne et al disclose the method for manufacturing the catheter structure substantially as claimed. However, Wijeratne et al are silent on the insertion of a first expander into the distal end of the main tube and a second expander into the proximal end of the guide tube and on the extraction of the first and second expanders once the sealing has been performed. Miraki teaches inserting expanders into the ends of tubes that will become a lumen for a guidewire or an inflation lumen and removing the expanders after use in the same field

of endeavor of using heat-sealing to join the different sections of a catheter structure (lines 51-68 of column 7 and line 40 of column 12 to line 52 of column 13). The expanders maintain the shape of the tubes in the area or zone where the tubes are to be sealed. It would have been obvious to one having ordinary skill in the art at the time the invention was made to form the lumens of Wijeratne et al by using expanders as taught by Miraki as both Wijeratne et al and Miraki disclose securing the ends of the tubes at a seal area (lines 1-36 of column 13 of Wijeratne et al and line 42 of column 5 to line 14 of column 6 of Miraki) and Miraki teaches that it is well known to use expanders to form lumens when using heat-sealing to form a catheter structure. It also would have been obvious to one having ordinary skill in the art at the time the invention was made to extract or remove the expanders once the sealing has been performed as it is well known in the art of sealing components of a catheter assembly using expanders to remove the expanders once the sealing step has been performed as the role of the expanders is only to maintain the shape of the tubes in the area of sealing while the heat-sealing operation is being performed.

Even though Wijeratne et al disclose at least a part of the deflected and inclined portion of the main tube (32) being inserted into the distal tube flared proximal end (100) so that a portion (at 26) of the guide tube (23) near the proximal end of the guide tube rests on a section of the outside of the deflected and inclined portion, Wijeratne et al are silent on the specifics the proximal end of the guide tube extending past the deflected and inclined portion of the main tube. Also, even though Wijeratne et al teach fixing the distal end (37) of the main tube, the proximal end (26) of the guide tube, and the flared

proximal end (at 38) of the distal tube to one another by means of a heat-sealing operation such that there is a union of the guide tube and the flared proximal end of the distal tube and a union of the guide tube and the deflected and inclined portion of the main tube, Wijeratne et al are silent on the specifics of beveling the guide tube proximal end at an angle formed by following a straight line from the union of the guide tube and the flared proximal end of the distal tube to the union of the guide tube and the deflected and inclined portion of the main tube. Dirks et al disclose a method for manufacturing a dilation catheter structure where a guide tube (76) is inserted into a catheter (62) and a proximal end of the guide tube is sealed in an opening or a deflected and inclined portion (82) of the catheter by a heat-sealing operation (lines 44-64 of column 3). The proximal end of the guide tube rests on the outside of the deflected and inclined portion as seen in Figure 3. Since Dirks et al disclose that there is a protruding section of the guide tube that is beveled off after the sealing step to form a smooth transition with the outer wall of the catheter, this indicates that the proximal end of the guide tube extended past the opening or the deflected and inclined portion (82) in the catheter before the sealing step and the beveling step. It would have been obvious to one having ordinary skill in the art at the time the invention was made to insert the deflected and inclined portion of the main tube into the distal tube flared proximal end of Wijeratne et al such that the proximal end of the guide tube extends past the opening or the deflected and inclined portion of the catheter as taught by Dirks et al as both Wijeratne et al and Dirks et al disclose manufacturing a dilation catheter where a proximal end of the guide tube rests on the outside of the deflected and inclined portion and Dirks et al

teach that it is well known to initially insert the guide tube into the catheter such that the guide tube extends past the deflected and inclined portion and then, once the guide tube is sealed to the catheter, to bevel the guide tube to form a smooth transition with the outer wall of the catheter. Dirks et al also disclose that the proximal end of the guide tube is beveled at an angle formed by following a straight line from the union of the guide tube and a distal section of the opening to the union of the guide tube and a proximal section of the opening (Figure 3). It would have been obvious to one having ordinary skill in the art at the time the invention was made to bevel the proximal end of the guide tube of Wijeratne et al (which now extends past the deflected and inclined portion of the main tube as taught by Dirks et al) at an angle following a straight line from the union of the guide tube and the flared proximal end of the distal tube to the union of the guide tube and the deflected and inclined portion of the main tube which is similar to the proximal end of the guide tube being beveled at an angle formed by following a straight line from the union of the guide tube and a distal section of the opening to the union of the guide tube and a proximal section of the opening as taught by Dirks et al as Dirk et al teach that it is well known to bevel the protruding section of the guide tube to allow for the guide tube to form a smooth transition with the outer wall of the catheter (lines 60-64 of column 3).

As to claim 27, Wijeratne et al, Miraki, and Dirks et al disclose the method for manufacturing the catheter structure substantially as claimed. Even though Wijeratne et al in view of Miraki and in view of Dirks et al disclose the step of extracting the expanders and the step of beveling the guide tube proximal end once the sealing has

been performed, Wijeratne et al, Miraki, and Dirks et al are silent on the step of beveling the guide tube proximal end being carried out after the step of extracting the expanders. It would have been obvious to one having ordinary skill in the art at the time the invention was made to bevel the guide tube proximal end after the extracting of the expanders as it would be difficult and impractical to bevel the proximal end of the guide tube while an expander is present in the guide tube.

5. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al in view of Miraki and in view of Dirks et al as applied to claim 24 above, and further in view of Fitzmaurice et al (U.S. Patent No. 5,823,995). Wijeratne et al, Miraki, and Dirks et al disclose the method for manufacturing the catheter structure substantially as claimed. However, Wijeratne et al, Miraki, Dirks et al are silent on the specifics of inserting the guide tube into the distal tube before the step of inserting the two expanders. Fitzmaurice et al disclose a method of manufacturing a catheter structure where different components of the catheter structure are assembled before the insertion of expanders or mandrels. Specifically, the wire assembly (14, 50) is placed in the proximal shaft (32) before the mandrel (37) is inserted between the wire assembly and the proximal shaft (lines 36-48 of column 4). It would have been obvious to one having ordinary skill in the art at the time the invention was made to insert the guide tube into the distal tube of Wijeratne et al before inserting the expanders as taught by Fitzmaurice et al as Fitzmaurice et al teach that it is well known to assembly the different components of a catheter structure before inserting expanders into the components.

Response to Arguments

6. Applicant's arguments with respect to claims 23-25 and 27 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BHISMA MEHTA whose telephone number is (571)272-3383. The examiner can normally be reached on Monday through Friday, 7:30 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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